

## **REMARKS**

### **A. Allowed Claim**

Claim 4 is noted as being allowed.

### **B. Amendment to Claim 1**

Claim 1 is amended to clarify the text of the claim.

### **C. Remaining Rejections**

In the Office Action, Claims 1, 3 and 5 – 7 are rejected as anticipated by WO 01/41671 A2 (“Cigaina”). Claim 2 is rejected as obvious in view of Cigaina. Claims 8 – 12 are rejected as obvious over Cigaina in view of U.S. patent application Publication No. US 2002/0193842 A1 (“Forsell”).

Applicants respectfully request reconsideration of any rejection based on Cigaina. Cigaina (alone or in combination with any reference) does not suggest placement on an esophagus:

- Cigaina does not show or suggest a treatment for GERD.
- Cigaina does not show or suggest placing a band on an esophagus.

### **D. Cigaina Does Not Show or Suggest a Treatment for GERD**

#### **a. A Different Medical Method Precludes a Rejection Based on Anticipation**

All claims are directed to a treatment of gastro-esophageal reflux disease (GERD). Cigaina is directed solely to a treatment of obesity. (See, e.g., Cigaina, p. 1, lines 5 – 8). There is no mention in Cigaina of a GERD treatment. This difference precludes a finding of anticipation.

In Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 77 U.S.P.Q. 2d 1321 (Fed. Cir. 2005), the Court reversed a finding of anticipation as to method claims directed to treating or preventing skin damage (sunburn) using an old lotion described in the prior art for cosmetic use on skin. The district court had concluded that a single prior art reference (Pereira) anticipated certain of the claims of one of the patents in suit (i.e., the ‘693 patent). Pereira disclosed cosmetic compositions for topical applications. The district court found anticipation because the

compositions of Pereira included all the various ingredients in the concentrations claimed in the '693 patent. The district court concluded the topical application of the prior art compositions would necessarily yield the claimed skin benefits of the '693 patent.

The Court upheld an anticipation finding as to claims 8 – 13 of the '693 patent. These claims merely required application of the composition to exposed skin surface. On the other hand, claims 1 – 4 and 7 recited application of a composition to “skin sunburn”. The Court reversed the anticipation finding as to these claims.

Claim 1 of the '693 patent, from which claims 2-4 and 7 ultimately depend, specifically recites application of the fatty acid ester to “skin sunburn.” This claim term raises a different problem. The issue is not, as the dissent and district court imply, whether Pereira’s lotion *if applied* to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.* that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. New uses of old products or processes are indeed patentable subject matter. *See* 35 U.S.C. § 101 (2000) (identifying as patentable “any new and useful improvements” of a process, machine, manufacture, etc.); *In re King* (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well.

Claim 1 of the '693 patent recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn. The district court’s inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira’s lotion, i.e., topical application, does not suggest application of Pereira’s lotion to skin sunburn. In other words, the district court’s inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application *to skin sunburn*, this court reverses the district court’s holding that Pereira anticipates claims 1-4 and 7 of the '693 patent.

432 F.3d at 1328, 77 U.S.P.Q. 2d at 1378 (citations omitted, italicization original, underlining added).

**b. A Treatment for Obesity Would Not Suggest a Treatment for GERD**

The concept of treating obesity with a gastric band is to create a small gastric pouch to accelerate a feeling of fullness. Such a small pouch increases the likelihood of gastric contents passing up into the esophagus. Therefore, a treatment for obesity teaches away from a treatment for GERD. See, also, Sharma Declaration, ¶ 6.

**E. Cigaina Does Not Show Or Suggest Placing A Band On An Esophagus**

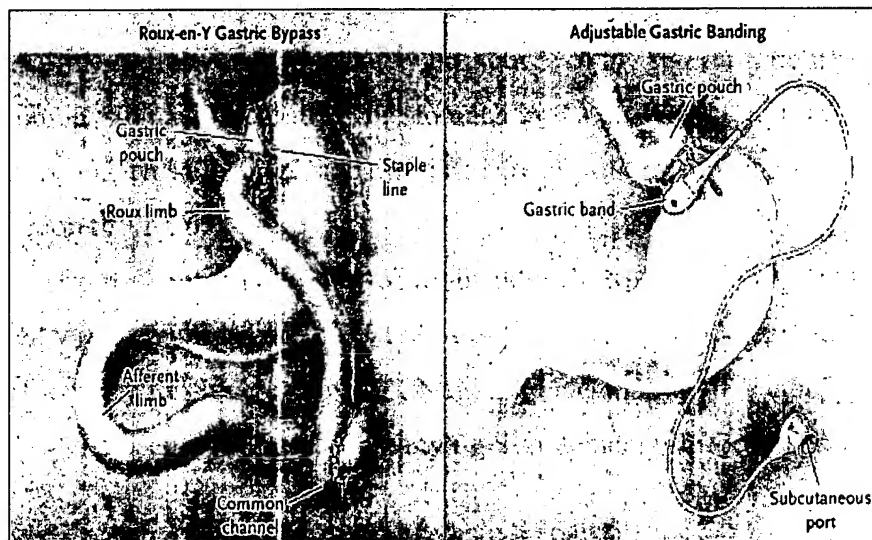
**a. The Examiner's Reliance Upon Fig. 6 in the Office Action Is Misplaced**

On page 3 of the Office Action, the Examiner shows a figure labeled "Fig. 6". The Examiner states "If a pouch was to be formed [by Cigaina] it would look like the attached figure [Fig. 6]". (Office Action, p. 2). This statement is incorrect.

The Office Action does not identify the source of the figure. The figure shows a band 20 placed around the stomach separating the stomach into a proximal one-third portion and a distal two-thirds portion. These relative size estimates are approximations based on the undersigned's visual inspection of Fig. 6.

Fig. 6 (from a source unknown to Applicants) shows, at best, a gross exaggeration of a pouch formed with a gastric band to treat obesity. A more realistic depiction is found in Steinbrook, "Surgery for Severe Obesity", New England Journal of Medicine, Vol. 350, pp. 1075 – 1079 (2004) (enclosed with the accompanying Supplemental Information Disclosure Statement).

The following is reproduced from p. 1078 of the Steinbook article.



The drawing on the left shows a gastric pouch formed by a gastric bypass surgery (a so-called “Roux-en Y” procedure). The drawing on the right shows a gastric pouch formed by a gastric band (like the band depicted in Cigaina).

The text accompanying the drawing on p. 1078 states “In both procedures, the gastric pouch is generally less than 30 ml in volume”. (Emphasis added). The Examiner will take note that 1 tablespoon is about 14.8 milliliters. Therefore, a gastric pouch formed by a gastric band is generally less than about 2 tablespoons – less than the volume of an adult’s thumb.

Such a small volume is difficult to draw without exaggeration in a drawing. Therefore, a noticeable bulge or absence thereof in Figs. 2 and 4 in Cigaina is not meaningful. The larger scale drawing (Fig. 5B) of Cigaina shows such a bulge.

Clearly, Fig. 6 on page 3 of the Office Action is a gross exaggeration.

**b. The Figures of Cigaina Do Not Show ANY Portion of a Band on an Esophagus**

**i. Standards for Interpreting Drawings**

In the Office Action (p. 2), the Examiner states “The band of Cigaina is placed on the esophagus as shown in the figures.” This is factually and legally incorrect.

M.P.E.P. § 2125 “Drawings as Prior Art” states, in pertinent part (citations omitted):

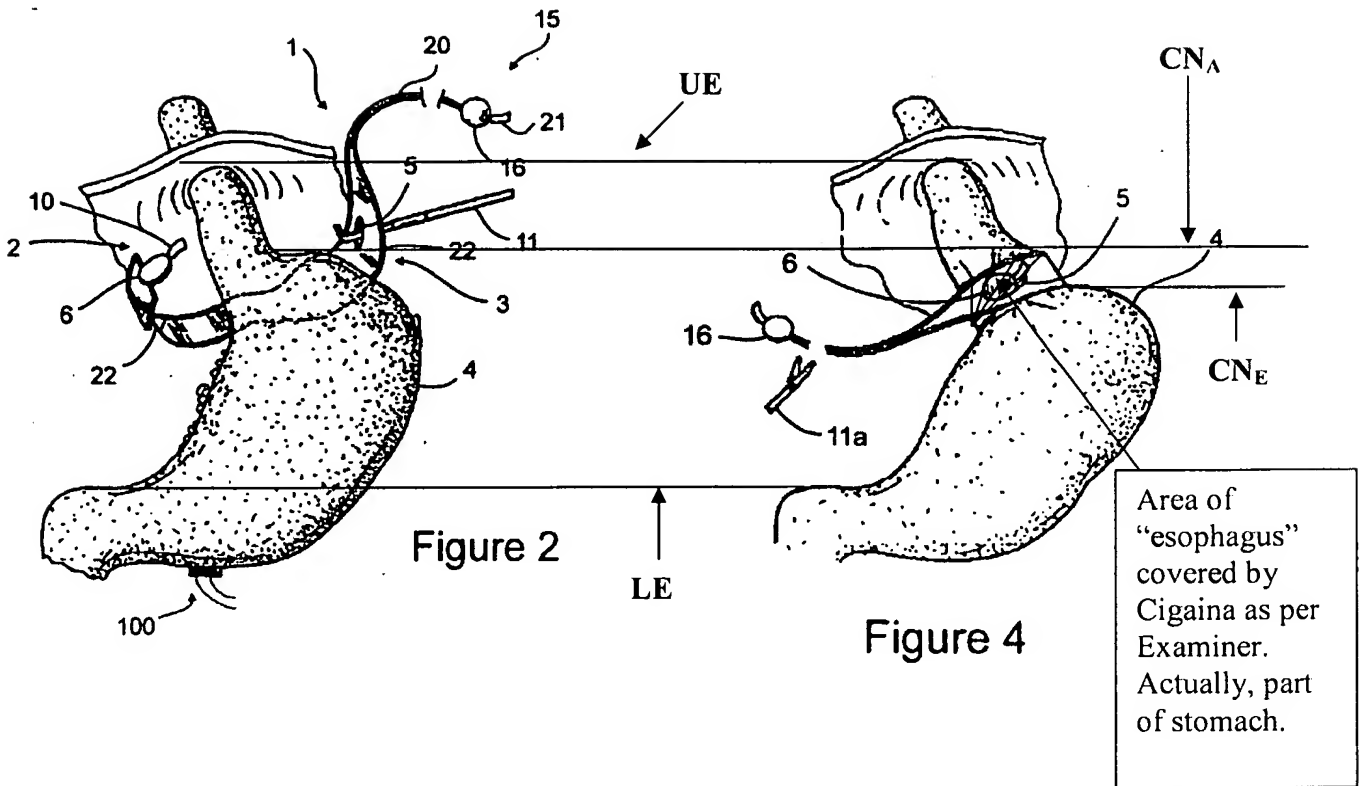
Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. However, the picture must show all the claimed structural features and how they are put together. ... .

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.

**ii. Figs. 2 and 4 of Cigaina Do Not Clearly Show a Band on an Esophagus**

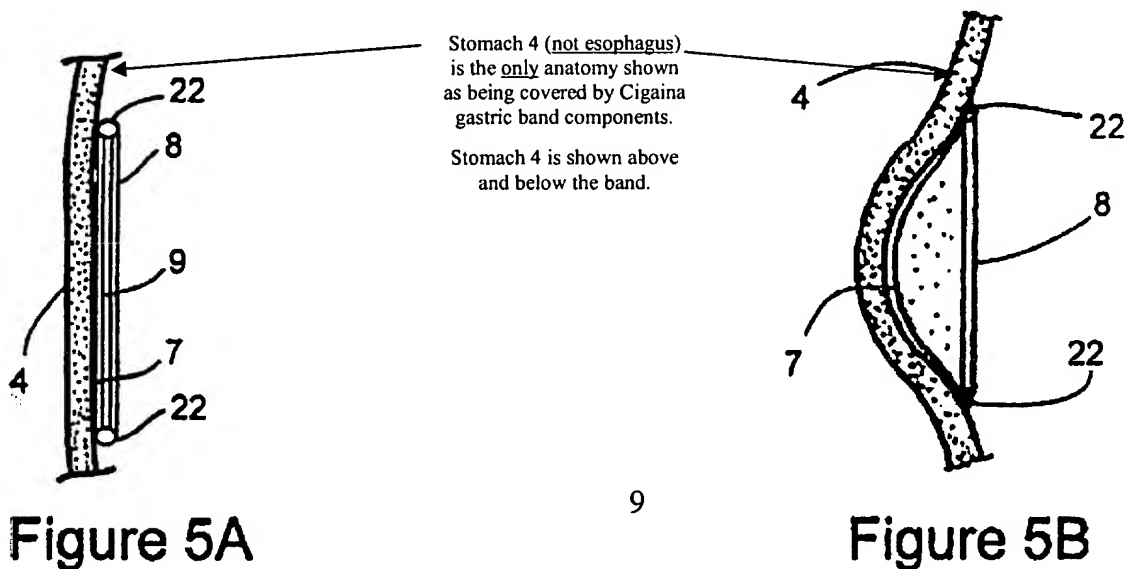
Mindful of the above M.P.E.P. admonitions, Applicants have already demonstrated that Figs. 2 and 4 of Cigaina do not “clearly show” the structure and method of the rejected claims.

The following is reproduced from Applicants March 9, 2006 “AMENDMENT UNDER 37 C.F.R. § 1.116”. It refutes the Examiner’s suggestion that Cigaina shows a band on the esophagus.



iii. Figs. 5 and 5A of Cigaina Clearly Show a Band Only on a Stomach with No Part of the Band on an Esophagus

More compelling than a comparison of Figs. 2 and 4 of Cigaina is a comparison of Figs. 5A and 5B. Unlike Figs. 2 and 4, Figs. 5A and 5B are of a scale and include labeling which permit a clear interpretation. In these figures, the band is shown deflated (Fig. 5A) and inflated (Fig. 5B) over the stomach only (element number 4) with no reference being made or shown to any structure overlying the esophagus.



**c. The Text of Cigaina Gives No Teaching or Suggestion to Place the Band of Cigaina Over any Portion of an Esophagus**

In the Office Action (p. 2), the Examiner states "... Cigaina show[s] placing a band that results in the relocation of the Cardiac notch, a lengthened esophagus , ...". This is factually incorrect. In addition to not being shown in the drawings (as discussed above), such remarks are not supported by the text of Cigaina.

A careful review of the text of Cigaina reveals no reference to placement of any portion of the band on the esophagus. The representative text passages of Cigaina are:

- P. 1, line 6 – 8: "The present invention relates to a removable gastric band which can be used to control obesity by allowing control ... of the diameter of a patient's stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, lines 10 – 12: The invention is a "gastric band comprising an elongated body ... to close around a portion of the stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, line 19: The elongated body closes "around a section of the stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 2, lines 27 - 30: The gastric band is positioned and locked "around a section of the stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 3, line 1 – 2: The gastric band is adjusted "to control the stomach's diameter in the section of the patient's stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 4, lines 28 – 30: The gastric band surrounds "a portion, preferably the proximal tract, of the patient's stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 5, lines 2 – 3: "Once locked into place, the gastric band 1 completely encircles and compresses a portion of the patient's stomach." (Emphasis added. Note, no mention of placement on esophagus).
- P. 6, lines 3 – 4: "Compression of the stomach using the gastric band of the present invention allows for a reduction of the stomach volume as desired."
- P. 8, lines 13 – 14: "The elongated body is inflated until the desired degree of compression of the stomach occurs." (Emphasis added. Note, no mention of placement on esophagus).
- P. 8, lines 28 – 30: "Using such a technique, the diameter of the gastric constriction provided by the gastric band can be modified or adjusted as desired." (Emphasis added. Note, no mention of placement on esophagus).
- P. 9, line 32: The expandability of the device "is linked to the limit of compressibility of the gastric walls ...". (Emphasis added. Note, no mention of placement on esophagus).

Clearly, Cigaina is limited to an improvement in old and well-known gastric bands to treat obesity. Such bands are disclosed in the present application on page 5 beginning at line 5. Cigaina only purports to describe a gastric band with enhanced removability.

**F. One of Ordinary Skill in the Art Recognizes that Cigaina Does Not Show or Suggest Placement of ANY Portion of the Band of Cigaina on an Esophagus**

In the record is the Declaration of Dr. Virender Sharma (“Sharma Declaration”). Dr. Sharma is a medical doctor. He is a gastroenterologist at the Mayo Clinic.

Dr. Sharma’s expertise extends to knowledge of gastric banding surgeries, procedures for the treatment of gastroesophageal reflux disease (GERD) and treatments for obesity.

As an expert, he has reviewed Cigaina. He notes that Cigaina is limited to the treatment for obesity with no suggestion for the use of Cigaina to treat GERD. (Sharma Declaration, ¶ 7). He also notes that upon inspection of the Cigaina publication, no portion of the band of Cigaina is placed above the cardiac notch or on the esophagus. (Sharma Declaration, ¶ 6). He further opines that such a placement would not be suggested by Cigaina since it would defeat the intent of gastric banding. (Sharma Declaration, ¶ 6).

The Examiner dismisses the Sharma Declaration saying “The statement of the declaration does not provide evidence of no portion of the band of Cigaina is placed above the cardiac notch or on the esophagus.” This is factually incorrect.

In direct contradiction to the Examiner’s remarks, the Sharma declaration states:

In placement of gastric bands such as Cigaina, no portion of the band is placed above the cardiac notch or on the esophagus. Such a placement is not shown in Cigaina. Further such a placement would not be suggested by Cigaina since such a placement would defeat the intent of gastric banding – namely, formation of a small stomach pouch above the band connected by a greatly reduced passageway to the remainder of the stomach.

Sharma Declaration, ¶ 6 (emphasis added).

The foregoing remark of Dr. Sharma is evidence. It is a direct observation by one of ordinary skill in the art.

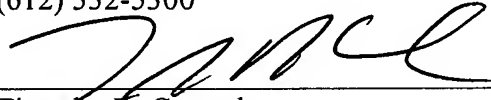
**G. Conclusion**

For the reasons given above, Applicants respectfully submit this application is now in condition for allowance. Reconsideration and Notice of Allowance are solicited.

If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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